UNITED STATES SOUTHERN DIS				
LOUIS REED, JR., - against -		Plaintiff,	X : : : : :	22-CV-8578 (VSB) <u>OPINION & ORDER</u>
PFIZER INC.,		Defendant.	: : :	

Appearances:

Louis Reed, Jr. Savannah, GA Pro se Plaintiff

Jason Reefer Pietragallo Gordon Alfano Bosick & Raspanti, LLP Pittsburgh, PA

Howard Alan Fried McGivney Kluger Clark & Intoccia, P.C. New York, NY Counsel for Defendant

VERNON S. BRODERICK, United States District Judge:

Plaintiff Louis Reed, Jr. brings this *pro se* diversity action against Defendant Pfizer, Inc. ("Pfizer"). Plaintiff alleges that he suffered injuries caused by a drug that Defendant developed and manufactured. Before me is Defendant's motion to dismiss Plaintiff's amended complaint. Because Plaintiff does not plausibly allege that Defendant manufactured the drug he took, or that the drug caused his injuries, Pfizer's motion is GRANTED.

I. Factual Background¹

Plaintiff Louis Reed, Jr. is a resident of Georgia born in 1954. (*See* Doc. 5 ("Am. Compl.") 7.)² He alleges that in February 2021, Dr. Jonathan Lanham prescribed him "Atorvastatin Calcium Tablets." (*Id.* 5.) Atorvastatin calcium is the generic name of the drug branded as Lipitor; the drug is approved for lowering cholesterol. *See* U.S. Pat. & Trademark Off., *Drug Patent & Exclusivity Study* 28 (June 25, 1998), https://perma.cc/ZTW4-V8Z8.³ Plaintiff alleges that Defendant Pfizer "manufactured," "developed," and "owns" the drug atorvastatin calcium. (Am. Compl. 4–5.)⁴

Beginning in March 2021, Plaintiff began to experience "pain" and "heavy legs muscle breakdowns all over his entire body." (Am. Compl. 5.) That month, Plaintiff visited Dr. Charles Degenhardt, who "arranged for a muscle biopsy" of his right thigh. (*Id.*) Plaintiff alleges that the results of the biopsy "determined that Plaintiff . . . suffered drug/toxin-induced myopathy" from atorvastatin calcium. (*Id.*) The biopsy results demonstrate that atorvastatin "caused [his] immune system to attack every organ in [his] body," and that because of the atorvastatin, Plaintiff's body "treated [his] organs and muscles as Transplant organs." (*Id.*) "Plaintiff asserts

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¹ Except where otherwise noted, I draw these facts from Plaintiff's amended complaint. (Doc. 5.) I assume the truth of Plaintiff's allegations for purposes of this motion. *See Kassner v. 2nd Ave. Delicatessen Inc.*, 496 F.3d 229, 237 (2d Cir. 2007). My references to these allegations should not be construed as findings of fact, and I make no such findings.

² Plaintiff's amended complaint includes a pro se complaint form, a supplemental narrative, and various attachments. Pincites to the amended complaint refer to the pages given the amended complaint by the court's electronic filing system.

³ The study from the U.S. Patent & Trademark Office is publicly available on their website. I may therefore take judicial notice of it. *See In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 208 (S.D.N.Y. 2012) ("[I]t is well established that courts may take judicial notice of publicly available documents on a motion to dismiss.").

⁴ Pfizer denies these allegations but accepts them as true for purposes of resolving the motion to dismiss. (*See* Doc. 22 at 2 n.2.)

that stemming from the prescribed drug Atorvastatin Calcium Tablets, [he] has to undergo Chemotherapy Care for the rest of his life." (*Id*.)

Plaintiff attached the "Final Diagnosis" of his biopsy to his amended complaint. (*See* Am. Compl. 7–10.)⁵ This medical record, dated September 23, 2021, stated that Plaintiff "had previously been on . . . atorvastatin," but it "ha[d] since been discontinued." (*Id.* 8.) The record further stated that the "biopsy demonstrates the presence of an active myopathic process," a finding "most consistent with an immune-mediated necrotizing myopathy (IMNM) related to anti-SRP antibodies." (*Id.* 7.) The report also stated "[a]dditional considerations in this case include . . . possible drug/toxin-induced myopathy (i.e. statin medication)," noting that this was "less likely given [Plaintiff's] clinical history." (*Id.*)

II. Procedural History

Plaintiff initiated this action on November 30, 2021 by filing a complaint in the United States District Court for the Eastern District of New York, asserting a product-liability claim against Pfizer, Inc. and a negligence claim against Dr. Lanham. (*See* Doc. 1.) Since the complaint pled that Plaintiff and Dr. Lanham were Georgia residents, Judge Kiyo Matsumoto of the Eastern District of New York dismissed the complaint on May 9, 2022 for lack of complete diversity and therefore lack of subject-matter jurisdiction, granting Plaintiff leave to refile. (*See* Doc. 4.) Plaintiff filed the operative amended complaint on August 10, 2022, naming only Pfizer, Inc. as Defendant. (Am. Compl. 1.) On September 28, 2022, Judge Matsumoto transferred the case to this District, as Pfizer's principal place of business is located here. (*See* Doc. 6.) On October 13, 2022, the case was assigned to me.

⁵ I may consider this extrinsic document because Plaintiff is proceeding pro se and the document is "consistent with the allegations in the complaint." *Gayot v. Perez*, No. 16-CV-8871, 2018 WL 6725331, at *4 (S.D.N.Y. Dec. 21, 2018) (internal quotation marks omitted); *see also id.* (collecting cases); *accord Smith v. Westchester Cnty.*, No. 19-CV-3605, 2021 WL 2856515, at *2 (S.D.N.Y. July 7, 2021).

Following delays in effectuating service, which I excused, (*see* Docs. 9, 18, 19), on May 30, 2023 Defendant Pfizer filed a motion to dismiss the amended complaint, (Doc. 21), along with a supporting memorandum of law, (Doc. 22 ("Mem.")). On June 20, 2023, Plaintiff filed a memorandum of law in opposition to the motion. (Doc. 26 ("Opp'n").) On June 26, 2023, Defendant filed a reply. (Doc. 29 ("Reply").) On September 19, 2023, I issued a stay of discovery pending my decision on the motion to dismiss. (Doc. 43.)

III. Legal Standard

To survive a motion to dismiss under Rule 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A court takes the well-pled facts in a complaint as true, draws all reasonable inferences in the plaintiff's favor, and ignores any "legal conclusions" among the factual allegations. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Dismissal is proper when "the allegations in a complaint, however true, could not raise a claim of entitlement to relief" as a matter of law. *Twombly*, 550 U.S. at 558.

Even after *Twombly* and *Iqbal*, a "document filed pro se is to be liberally construed and a pro se complaint, however inartfully pleaded, must be held to less stringent standards than formal pleadings drafted by lawyers." *Boykin v. KeyCorp*, 521 F.3d 202, 214 (2d Cir. 2008) (quoting *Erickson v. Pardus*, 551 U.S. 89, 94 (2007) (per curiam)). Further, pleadings of a pro se party should be read "to raise the strongest arguments that they suggest." *Brownell v. Krom*, 446 F.3d 305, 310 (2d Cir. 2006) (quoting *Jorgensen v. Epic/Sony Recs.*, 351 F.3d 46, 50 (2d Cir. 2003)).

Nevertheless, dismissal of a pro se complaint is appropriate where a plaintiff fails to state a plausible claim supported by more than conclusory allegations. *See Walker v. Schult*, 717 F.3d 119, 124 (2d Cir. 2013). In other words, "the duty to liberally construe a plaintiff's complaint is

not the equivalent of a duty to re-write it." Geldzahler v. N.Y. Med. Coll., 663 F. Supp. 2d 379, 387 (S.D.N.Y. 2009) (internal quotation marks and alterations omitted).

IV. **Discussion**

Defendant argues that—assuming Georgia law applies to this action—Plaintiff has not plausibly alleged any element of a product-liability claim. I agree that Georgia law applies, and that Plaintiff has failed to plausibly allege a product-liability claim against Pfizer.

"Federal courts sitting in diversity apply the choice of law rules of the forum state." Architectronics, Inc. v. Control Sys., 935 F. Supp. 425, 431 (S.D.N.Y. 1996) (citing Klaxon Co. v. Stentor Elec. Mfg. Co., 313 U.S. 487, 496 (1941)). "In product liability actions, New York courts apply the law of the place of the injury." Dorris v. Danone Waters of Am., 711 F. Supp. 3d 179, 194 (S.D.N.Y. 2024) (citation omitted). Here, all of Plaintiff's alleged injuries occurred in Georgia. (See Am. Compl. 5, 7–10.) Thus, Georgia law applies to this action.

Plaintiff alleges that atorvastatin calcium (1) "poisoned" him, (Am. Compl. 4); (2) is "defective"; (3) "should be removed off the public medication markets"; and (4) is "factually a threat to mankind" (Opp'n 2). In light of these allegations and reading the amended complaint to raise the strongest possible arguments on Plaintiff's behalf, see Brownell, 446 F.3d at 310, I read the complaint to assert two theories of liability under Georgia law: (1) strict liability, see O.C.G.A. § 51–1–11(b)(1), and (2) negligence, see Brazil v. Janssen Rsch. & Dev. LLC, 196 F. Supp. 3d 1351, 1361–62 (N.D. Ga. 2016). I address each of these theories in turn.

A. Strict Liability

Georgia's product-liability statute provides:

The manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort, irrespective of privity, to any

⁶ Plaintiff does not dispute that Georgia law applies.

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natural person who may use[,] consume, or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

Brazil, 196 F. Supp. 3d at 1357 (quoting O.C.G.A. § 51–1–11(b)(1)). "To state a claim for strict liability," under this statute, "the plaintiff must show that (1) the defendant was the manufacturer of the product; (2) the product, when sold, was not merchantable and reasonably suited to the use intended, and (3) the product's defective condition proximately caused plaintiff['s] injury." *Id.* (citing Chicago Hardware & Fixture Co. v. Letterman, 510 S.E.2d 875, 877–78 (Ga. Ct. App. 1999); see also Whitehead v. Green, 879 S.E.2d 698, 710 (Ga. Ct. App. 2022). "[T]here are three general categories of product defects: 'manufacturing defects, design defects, and marketing/packaging defects." Whitehead, 879 S.E.2d at 710 (quoting Banks v. ICI Americas, Inc., 450 S.E.2d 671, 672 (Ga. 1994)). I agree with Defendant that Plaintiff's allegations do not satisfy any element of Georgia's strict liability tort.

1. Manufacturer

First, Plaintiff has not plausibly alleged that Defendant "was the manufacturer of" the allegedly defective product, atorvastatin calcium. Brazil, 196 F. Supp. 3d at 1357. As Defendant points out, atorvastatin calcium has been available in generic form since at least 2011. See, e.g., Food & Drug Admin., Letter Approving Ranbaxy Inc. Application re Atorvastatin Calcium Tablets (Nov. 30, 2011), https://perma.cc/XAK2-LY78. (See also Doc. 22-2.) As of January 14, 2025, the FDA's Orange Book for generic equivalents to atorvastatin contains 187 entries. Food & Drug Admin., Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations for Atorvastatin (Jan. 14, 2025), https://perma.cc/CA2C-CS4M ("Orange Book"). To state this claim, Plaintiff must plausibly allege that Defendant, rather than another entity approved to manufacture atorvastatin calcium, was the manufacturer of the drug that he took that

allegedly caused his injuries. Plaintiff's amended complaint alleges only that he took "atorvastatin calcium," and does not contain any allegation to link the drug he took to Pfizer. (See generally Am. Compl.)

Further, I may consider documents attached to Plaintiff's opposition papers in resolving the instant motion. See Gayot v. Perez, No. 16-CV-8871, 2018 WL 6725331, at *4 (S.D.N.Y. Dec. 21, 2018) (explaining that a court may consider "documents that a pro se litigant attaches to his opposition papers" in resolving a motion to dismiss (internal quotation marks omitted)). Attached to his opposition to the motion dismiss the amended complaint, Plaintiff includes a photograph of the bottle of atorvastatin tablets that he took. (Opp'n 7.) A higher-quality scan of this image shows that Plaintiff's medication is labeled "Biocon" with National Drug Code ("NDC") 70377-029-11. (Doc. 27-1 at 8.) The FDA's NDC database listing corresponding to this NDC lists "Biocon Pharma Inc." as the "Labeler," see Food & Drug Admin., NDC Database Listing for 70377-029-11 (Jan. 14, 2025), https://perma.cc/5Q4E-GLBX, and the application linked to the Orange Book listing corresponding to this NDC lists "GRAVITI PHARMACEUTICALS PRIVATE LTD" as the full name of the applicant manufacturing this drug, Orange Book at 5 (application number ("Appl. No.") A209912). None of these entities refer to Defendant Pfizer as the manufacturer of the drug Plaintiff took, and Plaintiff does not allege otherwise.

Thus, Plaintiff fails to plausibly allege that Defendant Pfizer manufactured the drug that allegedly injured him. Although this failure warrants dismissal of each of Plaintiff's claims against Pfizer, I nonetheless examine each of his theories of liability.

2. Defect

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As discussed, Georgia law recognizes "three general categories of product defects: "manufacturing defects, design defects, and marketing/packaging defects." Whitehead, 879 S.E.2d at 710 (quoting Banks, 450 S.E.2d at 672). Plaintiff does not allege a "manufacturing defect," which is "a deviation [during manufacturing] from some objective standard or a departure from the manufacturer's specifications established for the creation of the product," Jones v. Amazing Prod., Inc., 231 F.Supp.2d 1228, 1236 (N.D. Ga. 2002), because he alleges that atorvastatin in general is dangerous, not that the particular atorvastatin he took is dangerous, (see Opp'n 2 (stating that atorvastatin "should be removed off the public medication markets")). He also does not allege that anything was defective about atorvastatin's "marketing" or "packaging". Whitehead, 879 S.E.2d at 710 (quoting Banks, 450 S.E.2d at 672). For example, Plaintiff's does not allege that Defendant "had a duty to warn about [a specific] risk," Brazil, 196 F. Supp. 3d at 1359 (internal quotation marks omitted).

Instead, Plaintiff alleges that the drug atorvastatin itself is generally defective, which is a "design defect[]" theory. *Whitehead*, 879 S.E.2d at 710 (quoting *Banks*, 450 S.E.2d at 672). To evaluate whether the design of a product is defective under Georgia law, courts use a "risk-utility analysis, in which there is a 'balancing of the risks inherent in a product design against the utility of the product so designed." *Id.* (alterations adopted). Plaintiff states that atorvastatin "poisoned" him, (Am. Compl. 4), that it is "defective," that it "should be removed off the public medication markets," and that it is "factually a threat to mankind," (Opp'n 2). Courts routinely dismiss design-defect claims based on similar allegations as too "general" and "conclusory" to support liability. *Henderson v. Sun Pharms. Indus., Ltd.*, No. 4:11-CV-60, 2011 WL 4024656, at *5 (N.D. Ga. June 9, 2011) (dismissing claim alleging that a drug "was defective in design" and

"was unreasonably dangerous in that its foreseeable risks exceeded the benefits associated with the designs or formulations of the product"); *see also, e.g., Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1344 (N.D. Ga. 2012) (concluding, based on similar allegations, that "plaintiff ha[d] not alleged any specific design or manufacturing defect" in either Pfizer's or Mylan's products).

Plaintiff's amended complaint fails to plausibly allege a design defect.

3. Causation

Finally, "because the complaint is silent as to a [specific] design or manufacturing defect, the Court cannot draw the reasonable inference that a design or manufacturing defect caused [Plaintiff's] injuries." *Moore*, 840 F. Supp. 2d at 1345 (citing *Hall v. Scott USA, Ltd.*, 400 S.E.2d 700, 701 (Ga. Ct. App. 1990)). Indeed, the medical report that Plaintiff submitted stated that his doctors thought it was "less likely," (Am. Compl. 7), as opposed to "plausible," *Twombly*, 550 U.S. at 570, that atorvastatin caused his medical difficulties. This is insufficient to defeat a motion to dismiss.

Plaintiff has not plausibly established any element of a claim under Georgia law for strict product liability. To the extent his complaint asserts such a claim, it is DISMSISED.

B. Negligence

Neither can Plaintiff's amended complaint withstand dismissal if I construe it to assert a claim for negligence. "Under Georgia law, a plaintiff asserting a negligence claim must prove the following elements: (1) [the defendant had] a legal duty to conform to a standard of conduct raised by the law for the protection of others against unreasonable risk of harm; (2) breach of this standard; (3) a legally attributable causal connection between the conduct and resulting injury; and, (4) some loss or damage flowing to the plaintiffs legally protected interest as a result of the alleged breach of the legal duty." *Brazil*, 196 F. Supp. 3d at 1361 (internal quotation marks

omitted); accord Moore, 840 F. Supp. 2d at 1351 (quoting Dixie Grp., Inc. v. Shaw Indus. Grp., 693 S.E.2d 888, 895 (Ga. Ct. App. 2010)). Plaintiff's amended complaint, construed to assert a negligence claim, cannot survive dismissal for the same reasons a strict liability claim fails, namely that Defendant did not manufacture the drug Plaintiff took, and that Plaintiff's allegations as to breach and causation are too conclusory to survive dismissal. See supra § IV.A.

V. Conclusion

For the foregoing reasons, Defendant's motion to dismiss is GRANTED, and the claims asserted in Plaintiff's amended complaint are DISMISSED.

The Clerk of Court is respectfully directed to terminate the pending motion at Doc. 21, to mail a copy of this Opinion & Order to Plaintiff at the address on file, and to close the case.

SO ORDERED.

Dated: February 18, 2025 New York, New York

> Vernon S. Broderick United States District Judge